In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 13-808V
(To be published)

JESSICA DEAN *and* RYAN DEAN, *on behalf of their minor child*, I.D., Petitioners, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Special Master Corcoran Filed: June 9, 2017 Decision without Hearing; Dismissal; Diphtheria-Tetanus-acellular Pertussis ("DTaP") Vaccine; Haemophilus Influenzae Type b ("Hib") Vaccine; Neurological Deficits.

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Darryl R. Wishard, U.S. Dep't of Justice, Washington, DC, for Respondent.

DECISION DENYING ENTITLEMENT[1]

On October 17, 2013, Jessica and Ryan Dean, as parents of I.D., a minor, filed a petition for compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program").[2] In it, the Deans alleged that I.D. developed "significant neurological deficits" as a result of receiving the Diphtheria-Tetanus-acellular Pertussis ("DTaP") and Haemophilus Influenzae Type b ("Hib") vaccines on February 24, 2011.

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[1] This decision will be posted on the United States Court of Federal Claims website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means the ruling will be available to anyone with access to the internet.** As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the published decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole decision will be available to the public in its current form. *Id*.

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended, 42 U.S.C. §§ 300aa-10 through 34 (2012) [hereinafter "Vaccine Act" or "the Act"]. Individual section references hereafter will be to § 300aa of the Act.

Although the matter was originally set for an entitlement hearing on March 14-15, 2017, the parties subsequently expressed a willingness to have the claim decided on the record, and therefore requested that it be taken off the trial calendar. The Deans have now filed a motion for a Ruling on the Record, dated December 12, 2016 (ECF No. 64) ("Mot."). Respondent reacted to the Motion and asked for dismissal of the claim on January 11, 2017 (ECF No. 65) ("Response"), and Petitioners then filed a reply in further support of their Motion on January 19, 2017 (ECF No. 66) ("Reply"). Having completed my review of the evidentiary record and the parties' filings, I hereby **DENY** Petitioners' Motion for the reasons stated below and **DISMISS** their claim.

I. Factual History

Vaccination and Subsequent Medical History

I.D. was born on September 24, 2010, at full term via vaginal delivery with APGAR scores of 8/9. Ex. 2 at 81; Ex. 3 at 6. Her hearing and newborn screens were normal, and she was discharged after two days. Ex. 2 at 80-81. In the first several months of her life, I.D. was deemed to be developing normally overall, although a few problems – specifically, some initial growth and feeding issues, as well as an underlying heart murmur – were observed and addressed. Ex. 2 at 27, 29, 33, 35, and 74; Ex. 7 at 4.

On February 24, 2011, I.D. had a five-month visit with her pediatrician, Dr. Cornelia Franz, who noted I.D.'s continued normal growth and development. Ex. 2 at 24. At this time, I.D. received the vaccines at issue in this case: second doses of the DTaP and Hib vaccines. *Id.* She had received the first dose of these on December 21, 2010, without any reported reaction. Ex. 2 at 8, 10.

A little over three weeks passed before I.D. returned to Dr. Franz on March 17, 2011, for a sick visit to examine a rash. Ex. 2 at 23. At this time, I.D. was diagnosed with eczema, and though the treatment plan recorded in Dr. Franz's notes reflects an intent to wait on any further vaccines, the contemporaneous records make no express mention of any adverse reaction to the February 24, 2011, vaccines. *Id.* Mrs. Dean, however, has alleged that I.D. experienced an immediately-noticeable reaction after receiving the February 24th vaccines, characterized by screaming and then a fever, plus projectile vomiting. Ex. 1 (Dean Affidavit) at ¶ 5; Ex. 10 (Declaration of Dr. Franz ("Franz Decl.")) at ¶ 3. Mrs. Dean has also maintained that I.D. was thereafter uncharacteristically lethargic. Dean Affidavit at ¶ 6. Petitioners explained that two weeks later, I.D. began to make what they now recall as abnormal movements, but because she was their first child, they assumed it was normal infant activity (and therefore chose not to report their concerns to Dr. Franz at that time). Dean Affidavit at ¶ 7; Franz Decl. at ¶ 4.

Records from treatment I.D. received in April 2011 provide the first contemporaneous recording of concerns about I.D.'s development. Thus, the Deans took I.D. for another sick visit with Dr. Franz on April 12, 2011, at which time Mrs. Dean's observations of hand flapping were noted. Ex. 2 at 22. Dr. Franz recorded I.D.'s behavior at the appointment as "normal hand movement," however, and explained that I.D. moving her fingers when excited was normal. *Id.* The medical records also revealed that most of the appointment was spent reassuring Mrs. Dean that I.D. exhibited normal infant behavior. *Id.* Thereafter, at the six-month well-child visit with Dr. Franz on April 26, 2011, Mrs. Dean more directly expressed her concerns about I.D.'s abnormal hand movements, noting that the symptoms had started two months before (or in late February). *Id.* at 21. I.D.'s development and exam were normal, but she was referred to pediatric neurology for further evaluation of her movements. *Id.* at 21; 66. Dr. Franz stated that if the neurology examination was normal, I.D. should receive additional vaccinations at that time. *Id.* at 21.

On May 2, 2011, I.D. saw Dr. Ronald Davis, a pediatric neurologist, for evaluation of her "unusual movements." Ex. 2 at 66. Mrs. Dean showed Dr. Davis a video that displayed I.D. lifting her hands to and from her face and twisting her hands in a flailing-like maneuver. *Id.* Dr. Davis hypothesized that these episodes occurred whenever I.D. experienced a mood change, as he witnessed one of these episodes during the appointment. *Id.* However, Dr. Davis also observed that I.D. had no reports of experiencing any changes in her mental status, there was no sleepiness associated with these spells, and she otherwise appeared to have been developing normally (based on her records and examination). *Id.* Dr. Davis described I.D. as well-developed and healthy-appearing, and he found her to be neurologically normal. *Id.* at 67. On that same day, I.D. also underwent an EEG, which was completely normal. *Id.* at 68-69.

Given the above, Dr. Davis diagnosed I.D. with benign stereotypies of childhood, which he described as a nonthreatening condition similar to a childhood tic disorder, and he cleared her to receive further immunizations. Ex. 2 at 67. The Deans, however, remained concerned about the purported observed changes in I.D.'s physical movements, and they have maintained in fact statements filed after the initiation of this lawsuit that she had ceased verbalizing at six months of age (although the medical records do not reference this alleged developmental problem even at the time of Dr. Davis's examination, which occurred when I.D. was about eight months old). Dean Affidavit at ¶ 9; Franz Decl. at ¶ 5.

On June 29, 2011, I.D. had her nine-month well-child visit with Dr. Franz, who now noted (in addition to what she characterized as otherwise normal growth and development) that I.D. exhibited abnormal movements, reported as "tenses arms and legs when overstimulated . . . twitching." Ex. 2 at 19. Dr. Franz made the determination that further vaccination should be withheld, although she did not explain why. *Id.* However, she noted that this decision to pause

vaccinations should be revisited before I.D. was 12 months old, depending on resolution of her symptoms. *Id.*

This 12-month well-child visit occurred on September 26, 2011. Ex. 2 at 18. The medical history from that visit stated that I.D.'s "abnormal movements" had been observed five months after vaccinations (likely referring to the February vaccinations), and that I.D. still displayed some involuntary physical movements (which Dr. Franz observed during the visit), although the hand movements had largely resolved. *Id*. Otherwise I.D. displayed normal growth and development, and no other concerns about her health were noted. Dr. Franz repeated the earlier diagnosis of benign stereotypies of childhood to explain I.D.'s observed behaviors, and vaccines were deferred again until the 15-month visit if her abnormal movements had stopped. *Id.*

Dr. Franz also saw I.D. on October 20, 2011, after Petitioners brought her in for evaluation of pulling on her right ear and irritability after drinking milk. Ex. 2 at 17. Dr. Franz determined that I.D. had a possible milk sensitivity and recommended avoiding cow's milk. *Id.* I.D. was also seen for a fever and a urinary tract infection ("UTI") on October 28, 2011, and she was diagnosed with a likely early viral illness. *Id.* at 16. She was seen again on November 4, 2011, to re-check her urine levels following her UTI diagnosis. *Id.* at 15. Petitioners reported that I.D. had not had a fever or vomiting since the last visit, and she was generally improving. *Id.* The plan was to continue treatment for the UTI and practice good cleaning habits to prevent further infection. *Id.*

I.D. returned for her 15-month visit on December 28, 2011. Ex. 2 at 14. At this time, I.D. was noted to be sensitive to sounds and textures, and some abnormal movements were again reported and recorded. *Id.* I.D.'s growth, development, and physical exam were normal, however, as before. Dr. Franz raised the possibility of a sensory integration disorder, and I.D.'s vaccines were deferred yet another time. *Id.* at 14. The next relevant medical record is from I.D.'s March 28, 2012, 18-month exam. *Id.* at 13. The history from that visit noted that I.D. was now seeing an occupational therapist, but that her speech was improving. *Id.*

Treatment of I.D.'s Motor and Developmental Problems

I.D. received speech and occupational therapy in 2012 and 2013 for feeding issues and speech delay. Ex. 2 at 64; Ex. 4 at 74. Treatment records from this period identify her as a picky eater who could say 10 to 15 words. *See, e.g.,* Ex. 4 at 74. She was noted to have jaw and tongue weakness, and she had been recommended for speech therapy to address her expressive language delay. *Id.* Problems with sensory integration issues were also reaffirmed, and I.D.'s treaters proposed therapies targeted at making her comfortable with certain sounds and textures without significant aversion. *Id*.

Despite such treatments, I.D. was reported as displaying generally normal behavior during this time. *Id*. Her final occupational therapy visit was on August 5, 2013, at which time no reports of hand-flapping or other abnormal movements were reported (although they had been observed in 2012 and earlier in 2013). *Id.* at 2. I.D. continued to receive speech therapy into 2014. Ex. 9 at 4 (I.D. "was discharged from occupational therapy just recently according to mom").

Subsequent History and Reports of Post-Vaccination Adverse Event

The filed medical records reveal that beginning in 2013, Petitioners increasingly began reporting to treaters that I.D. had experienced a severe and noticeable reaction to her February 2011 vaccinations – even though the contemporaneous medical history does not support that recitation of events – and accordingly made requests for treatment adjustments. Thus, in connection with an occupational therapy treatment visit in January 2013, Mrs. Dean reported that I.D. had experienced an "initial reaction" to the February 2011 vaccines that moved into her arms and legs before seemingly resolving a year later. Ex. 4 at 72.

Then, on May 17, 2013, Dr. Franz proposed in writing that I.D. receive a permanent medical exemption from immunizations due to her purported adverse reaction. Ex. 2 at 10. On June 7, 2013, Mrs. Dean completed a VAERS[3] form, stating that I.D. had experienced an adverse event on February 24, 2011 (the day of vaccination), including hand flapping, arm tensing, fever, vomiting, and bruising; that her symptoms lasted over a year; and that she now suffered from a permanent disability. Ex. 8 at 1-3.

Petitioners thereafter continued to report the same factual history to subsequent treaters – which the treaters in turn relied upon. For example, on March 11, 2014, I.D. had another speech therapy visit, at which time Petitioners stated that I.D. had experienced a reaction to her five-month vaccines. Ex. 9 at 9. In June 2014, and after this case was filed, Dr. Franz signed a declaration in support of Petitioners' claim. *See generally* Franz Decl. Terming Petitioners "credible historians," Dr. Franz repeated their prior assertions (without reference to independent medical evidence) that I.D. had experienced a fever and screamed and cried inconsolably on the day of her vaccinations. *Id.* at ¶ 3. Based on this history (and again without offering independent corroborative evidence), Dr. Franz concluded that I.D. had suffered an encephalopathic event due to her vaccinations and that it was therefore proper to diagnose her with a "neuroencephalopathic reaction." *Id.* at ¶ 6.

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[3] VAERS stands for the Vaccine Adverse Event Reporting System, which allows doctors and patients to self-report any potential reactions to vaccines into a database. Centers for Disease Control and Prevention, *Vaccine Adverse Event Reporting System (VAERS)*, Vaccine Safety (last updated Aug. 28, 2015).

II. Expert Reports

A. *Dr. David Axelrod*

Petitioners' immunology expert, Dr. David Axelrod, has offered a medical theory attempting to causally connect I.D.'s February 2011 vaccinations and subsequent injury. *See* Report, dated October 15, 2014, ECF No. 30-1 (Ex. 12) ("Axelrod Rep."). Dr. Axelrod's theory largely proposes that I.D.'s vaccinations caused her developmental problems in two ways: first, through the general propensity of any vaccination (as a result of its stimulating impact on the innate immune system) to cause the upregulation of cytokines, which permits breaching of the blood-brain barrier and also affects the central nervous system; and second, due to the specific pathologic effects of the tetanus toxoid component of the DTaP vaccine on the brain.

Dr. Axelrod graduated from the University of Michigan Medical School in 1974 (after obtaining his bachelor's degree at Michigan as well). ECF No. 30-2 (Ex. 13) ("Axelrod CV") at 1. He completed two residencies in internal medicine, one at the University of Toronto and one at William Beaumont Hospital, followed by additional residencies with a fellowship in allergy, immunology, and rheumatology at McGill University. Axelrod CV at 1. He then served as a fellow for the National Institutes of Health in the Clinical Immunology Laboratory. *Id*. Dr. Axelrod is board certified in medicine, allergy and immunology, adult rheumatology, and medical laboratory immunology. *Id*. He currently works in private practice, with the vast majority of his patients having allergies, immunologic conditions, or autoimmune rheumatic diseases. *Id*. He does not appear, however, to conduct research in immunologic matters relevant to the theory expressed in this case.

Dr. Axelrod's theory comprises several separate but temporally-dependent elements. First, he opined that the vaccines at issue could cause the production of certain proinflammatory cytokines[4] immediately upon administration. Axelrod Rep. at 2. As shown by Kashiwagi et al., *Production of Inflammatory Cytokines in Response to Diphtheria-pertussis-tetanus (DPT), Haemophilus Influenzae Type B (Hib), and 7-valent Pneumococcal (PCV7) Vaccines*, 10 Human Vaccines & Immunotherapeutics 3:677-85 (2014) (Ex. 14) ("Kashiwagi"), vaccination results in elevated levels of four kinds of cytokines. *Id.* at 1; Kashiwagi at 678. Kashiwagi was an *in vitro* study comparing the levels of inflammatory cytokines in the sera of 61 vaccine recipients with febrile illness, against 18 recipients without febrile illness, 24 hours after vaccination (a fairly short period of time). *Id.* at 677. The study's authors began with peripheral blood mononuclear cell cultures and then introduced different combinations (separately or concurrently) of the DTaP, Hib,

[4] A cytokine is a generic term for non-antibody proteins released by one cell population on contact with specific antigen, which act as intercellular mediators, as in the generation of an immune response. *Dorland's Medical Dictionary* 466 (32nd ed. 2012) (hereinafter *Dorland's*). The term "proinflammatory" signifies that these cytokines are capable of stimulating inflammation. *Id.* at 1523.

and/or PCV7 vaccines in order to determine the levels of cytokine production in the cell cultures. *Id.*

Based on Kashiwagi, Dr. Axelrod maintained that the relevant proinflammatory cytokines involved in his theory are produced beginning six hours after vaccination and continue to increase until 24 hours following vaccination. Axelrod Rep. at 1. He also maintained that these elevated levels were found to persist after the 24 hour period. *Id.* Yet there are reasons to distinguish Kashiwagi from the present matter and to find that its conclusions are less compelling than Dr. Axelrod proposes. The results showing increased cytokine production were mainly seen with the combinations involving the PCV7 vaccine, which is not present in this case. Kashiwagi at 679. More significantly, Kashiwagi found no real difference between the two compared serum groups, beyond the fact that one particular cytokine was elevated in individuals experiencing a febrile illness. *Id.* at 680. Because Kashiwagi's authors admitted that "[v]accine-specific innate inflammatory responses . . . have not been sufficiently investigated regarding cytokine production using difference vaccines," they could not characterize this difference as significant (*id.* at 678), and ultimately concluded that more analysis was required. *Id.* at 683.

Dr. Axelrod also relied on T.J. Lawley et al., *A Prospective Clinical and Immunologic Analysis of Patients with Serum Sickness*, 311 New England J. of Med. 1407-13 (1984) (Ex. 18) ("Lawley"), to support the idea that autoimmune cutaneous and rheumatologic manifestations could occur anywhere from 10 to 25 days after exposure to an antigen. Axelrod Rep. at 2; Lawley at 1410. Dr. Axelrod thus contends that Lawley supports his proposition that I.D. experienced damage to her central nervous system immediately after her DTaP vaccination, followed by other autoimmune manifestations of that damage 15 days after, and therefore her onset would be within the 10 to 25 day timeframe that is posited as temporally appropriate.

Next, Dr. Axelrod proposed that certain of these cytokines (in particular TNF-α and Interleukin-6 ("IL-6") cytokines) purportedly increased by vaccine administration could subsequently disrupt the blood-brain barrier and cause it to become more permeable. Axelrod Rep. at 1; K. Rochfort et al., *Downregulation of Blood-Brain Barrier Phenotype by Proinflammatory Cytokines Involves NADPH Oxidase-Dependent ROS Generation*, 9 PLoS ONE 7:1-13 (2014) (Ex. 15) ("Rochfort"). He relies on Rochfort for support of this idea, which involved a study of primary-derived human brain microvascular endothelial cells (HBMvECs), and examined the effects of proinflammatory cytokines on the expression of interendothelial junction proteins, as well as the cytokines' effects on HBMvEC monolayer permeability. Rochfort at 2. Rochfort sought to confirm that either TNF-α or IL-6 cytokines could downregulate the expression of interendothelial adherens and tight junction proteins and elevate paracellular permeability, thus lending credence to the idea that these cytokines could possibly encourage blood-brain barrier dysfunction in

neurological diseases. Rochfort at 10-12.[5] However, it is important to note that Rochfort focused on IL-6 and TNF-α cytokines – different from the cytokine found to be significant in Kashiwagi (G-CSF). *See* Rochfort at 1; Kashiwagi at 1. Additionally, Rochfort required the continuous addition of cytokines via time and dose increases in order to obtain its specific results. Rochfort at 7. There is no suggestion in Rochfort that a vaccine reaction would be comparable, or that the experiment was intended to replicate a vaccine reaction – indeed, the article does not mention vaccines at all.

After cytokine production has been increased by vaccination and the blood-brain barrier has been rendered more permeable, Dr. Axelrod proposed that "blood borne chemicals, such as cytokines, as well as adaptive immune antibodies and cells, produced in the peripheral circulation," can now enter the central nervous system ("CNS") and act upon it. Axelrod Rep. at 1-2. There are two kinds of mediators that Dr. Axelrod specifically opined would harm the CNS and brain sufficient to cause a developmental problem. First, the same cytokine upregulation causing the blood-brain barrier's breach can in turn stimulate microglia,[6] which then produce additional harmful cytokines that affect the CNS cells. *Id.* at 2 (citing Rochfort at 7). Dr. Axelrod also referenced S.V. More et al., *Cellular and Molecular Mediators of Neuroinflammation in the Pathogenesis of Parkinson's Disease*, Mediators Inflamm. 952375 (2013) (Ex. 15) ("More"), for the proposition that the presence and production of proinflammatory cytokines in the brain can propagate and intensify neuroinflammation. More at 4.

Besides harm caused by cytokine upregulation attributable to vaccination generally, Dr. Axelrod's theory identified a vaccine-specific component as having the potential to cause injury. Dr. Axelrod posited that the tetanus toxoid component of the DTaP vaccine can pass through the now-breached blood-brain barrier. He alleged that the tetanus toxoid protein antigens introduced by the DTaP vaccine could then bind to certain gangliosides found on neuronal brain tissue.

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[5] The report filed by Petitioners' second witness, Dr. Harvey Cantor, proposes that the blood-brain barrier's permeability can be affected by the Bordetella Pertussis virus. *See* Cantor Report, dated May 26, 2015, ECF No. 39-1 (Ex. 24), at 2 ("[i]mmune-mediated increased permeability of blood vessel walls following B. Pertussis was described by Holt, et al., in 1961, and was suggested as an etiogenic pathway in encephalopathy following pertussis immunization in 1976 by S. A Amiel" (citing L. Holt et al., *Immunity in Mice to an Intracerebral Challenge of Bordetella Pertussis*, 59 J. Hyg. 373 (1961); S. Amiel, *The Effects of Bordetella Pertussis Vaccine on Cerebral Vascular Permeability*, 57 Br. J. Path. 653 (1976)).

The significance of such literature, however, is fairly limited in this case, since the acellular form of the Pertussis vaccine at issue herein is not comparable in effect to the whole-cell DPT version. *See, e.g., James v. Sec'y of Health & Human Servs.*, No. 09-284V, 2010 WL 4205699, at *11 (Fed. Cl. Spec. Mstr. Sept. 30, 2010) (both sides' experts agreed that the acellular form is less toxic than the whole-cell form, and subsequently adverse effects occur less often with the acellular form than with administration of the whole-cell form, although the acellular form still contains some toxicity); *Sucher v. Sec'y of Health & Human Servs.*, No. 07-58V, 2010 WL 1370627, at *36 (Fed. Cl. Spec. Mstr. Mar. 15, 2010) (discussing the differences between the whole-cell and acellular pertussis vaccines, specifically the use of a toxoid in the acellular version).

[6] Microglia are the small, non-neural, interstitial cells of mesodermal origin that form part of the supporting structure of the central nervous system. *Dorland's* at 1159.

Axelrod Rep. at 2; H.A. Louch et al., *Identification of a Binding Site for Ganglioside on the Receptor Binding Domain of Tetanus Toxin*, 41 Biochemistry 13644:13644-52 (2002) (Ex. 19); R.L. Schnaar et al., *Brain Gangliosides in Axon-Myelin Stability and Axon Regeneration*, 584 FEBS Lett 1741:1741-47 (2010) (Ex. 20). However, Louch only discusses the ability of the tetanus *toxin* to bind to gangliosides and neuronal cells – not the toxoid form contained in the DTaP vaccine. Louch at 13650-51. Dr. Axelrod nevertheless argued that the antibody and cellular response to the tetanus toxoid binding to neuronal gangliosides in the brain could cause damage to the surrounding tissues and allow for the development of a damaging immune response to other structures of the neurons. Axelrod Rep. at 2. This would theoretically occur through the mechanism of epitope spreading, which Dr. Axelrod described as the continuing and perpetuating ongoing destruction of the neuronal tissue. Axelrod Rep. at 3 (citing B. McRae et al., *Functional Evidence for Epitope Spreading in the Relapsing Pathology of Experimental Autoimmune Encephalomyelitis*, 182 J. Exp. Med. 75:75-85 (1995) (Ex. 22) ("McRae"), and A. Vojdani, *A Potential Link between Environmental Triggers and Autoimmunity*, 2014 Autoimmune Diseases (2014) (Ex. 23) ("Vojdani")).

Significantly, however, although Dr. Axelrod offered multiple literature items in support of his theory, none involves the propensity of *any* vaccine to cause the kind of developmental injury at issue in this case via the proposed process – or even the specific kind of injury at issue, regardless of whether it was vaccine-caused. For example, Dr. Axelrod cited McRae and Vojdani to support his description of epitope spreading. However, McRae is an animal study that focuses on T-cell reactivity and autoimmune diseases such as multiple sclerosis, while Vojdani examines autoimmune disorders generally and the environmental triggers which might cause individuals to develop modified proteins that in turn trigger antibody production and the inflammatory process that leads to autoimmune disorders. McRae at 83; Vojdani at 14. Thus, while these articles do discuss and generally support Dr. Axelrod's characterization of epitope spreading, they are largely unrelated to the injury claimed in this case and Dr. Axelrod's theory connecting I.D.'s specific vaccinations to said injury.

B. *Dr. Harvey Cantor*

In addition to Dr. Axelrod's opinion, the Deans have offered a three-page report from a pediatric neurologist, Dr. Harvey Cantor. *See* Report, dated May 26, 2015, ECF No. 39-1 (Ex. 24) ("Cantor Rep."). Dr. Cantor obtained his M.D. from the Washington University School of Medicine in 1962; he then completed a residency in pediatrics at the Stanford University School of Medicine from 1965-1966 and a fellowship in pediatric neurology from 1966-1969. ECF No. 39-2 (Ex. 25) ("Cantor CV") at 1-2. Dr. Cantor currently serves as a clinical professor in the Department of Physician Assistant Education at the St. Louis University School of Allied Health Professions, as well as a clinical professor of child neurology in the Department of Neurology at the St. Louis University School of Medicine. Cantor CV at 1-2. He is board certified in pediatrics,

psychiatry, and neurology with a special competence in child neurology. *Id.* at 2. He also maintains a private practice specializing in pediatric neurology in St. Louis, Missouri. *Id.*

Most of Dr. Cantor's report reiterated facts about I.D.'s treatment contained in the medical history. Cantor Rep. at 1-2. He largely accepted Dr. Franz's conclusions without additional elaboration – whether by citation to record points not already addressed or other evidence – as to why those conclusions are correct.

Although Dr. Cantor's specialty is neurology, the most substantive aspects of his report mirror Dr. Axelrod's assertions about the pathogenic capabilities of the DTaP vaccine. Thus, he offered some literature that he argued demonstrates the "relationship between pertussis immunization and severe/fatal medical complications," as well as neurological complications following pertussis immunization. Cantor Rep. 2. He proposed that one such article from the 1940s, Byers et al., *Encephalopathies Following Prophylactic Pertussis Vaccine*, 1 Pediatrics 437 (1948) (Ex. 26), demonstrates the possible neurologic damage that can result from pertussis vaccination. He also cited another article involving Acute Necrotizing Encephalopathy ("ANE"), which he maintained sheds light on the connection between DTaP and encephalopathy (although nowhere in his report did Dr. Cantor specifically opine that I.D. ever experienced a vaccine-induced encephalopathy, let alone ANE). *Id.* at 2 (citing X. Wu et al., *Acute Necrotizing Encephalopathy: An Underrecognized Clinicoradiologic Disorder*, 2015 Mediators of Inflammation (2015) (Ex. 30) ("Wu")). Dr. Cantor relied on the Wu article to allege both that vaccine-induced "[h]ypercytokinemia engenders proteolytic destruction of the blood-brain barrier (BBB) . . . which subsequently increases vascular permeability and causes brain edema, petechial hemorrhage, and necrosis," and also that ANE could occur secondary to even the DTaP vaccine (although according to the article, it would more likely be associated with the whole-cell Pertussis form). Wu at 2.

C. *Dr. Cornelia Franz*

As noted above, Dr. Cornelia Franz has provided a declaration in support of Petitioners' case. *See generally* Franz Decl. Dr. Franz's curriculum vitae was not filed, but her declaration reveals that she is a pediatric doctor at her own practice, The Franz Center, in Florida. Franz Decl. at 1. She received her M.D. from Bowman Gray School of Medicine in North Carolina, and she completed a pediatric internship in Kentucky followed by a pediatric residency at Shands Hospital at the University of Florida. *Id.* She also completed a fellowship in adolescent medicine at Cincinnati Children's Hospital. *Id.* The recitation of her experience does not mention any specific background in neurological issues specifically.

Dr. Franz's declaration largely tracked the medical records, but also included her explicit embrace of Petitioners' witness statements (wholly undocumented in the record) about I.D.'s

reaction to the February 2011 vaccines, deeming them credible. Franz Decl. at 1-2. Relying on such statements as well as her own treatment of I.D., Dr. Franz reached the conclusion that I.D. developed short-term brain inflammation following her vaccinations, which resulted in residual feeding difficulty and sensory issues. *Id.* at 2. She further noted that she later diagnosed I.D. with a neuroencephalopathic reaction to her four-month vaccinations (although the record shows this diagnosis did not occur contemporaneously with the receipt of these same vaccines), and placed a permanent medical exemption from additional vaccinations on I.D.'s chart. *Id.*

D. *Dr. Lawrence Brown*

Dr. Lawrence Brown is Respondent's sole expert, and he offered short written reports in response to the reports of Drs. Axelrod and Cantor. *See* Report, dated February 5, 2015, ECF No. 37-1 (Ex. A) ("First Brown Rep.") and Report, dated August 24, 2015, ECF No. 47-1 (Ex. E) ("Second Brown Rep.").

Dr. Brown is a pediatric neurologist at the Children's Hospital of Philadelphia. ECF No. 37-2 (Ex. B) ("Brown CV"). He received his M.D. in 1971 from the New York University School of Medicine, followed by a pediatric internship and pediatric residency at the Children's Hospital of Philadelphia in 1972 and 1973. Brown CV at 1. He also completed a fellowship in pediatric neurology at the Children's Hospital of Philadelphia from 1973-74 and 1976-78. *Id.* Dr. Brown also currently serves as an associate professor of neurology and pediatrics at the University of Pennsylvania School of Medicine, as well as the co-director of the Pediatric Regional Epilepsy Program and Pediatric Neuropsychiatry Center at the Children's Hospital of Philadelphia. *Id.* at 2. He is board certified in pediatrics, psychiatry, and neurology with special competence in pediatric neurology and sleep medicine. *Id.*

Dr. Brown's first report responded solely to Dr. Axelrod's opinion, while also offering a counter-reading of the medical records based upon his expertise as a pediatric neurologist. Dr. Brown largely accepted the view of Dr. Davis (himself a pediatric neurologist, as opposed to Dr. Franz) that I.D.'s post-vaccination behaviors were benign stereotypies unconnected to the February 2011 vaccines. First Brown Rep. at 3. Dr. Brown otherwise challenged Dr. Axelrod's opinion, noting that Dr. Axelrod provided nothing linking vaccination with motor stereotypies, and stressing that I.D.'s alleged immediate reaction to the vaccines (as set forth in Mrs. Dean's witness statement) does not establish an encephalopathy or any other damage to the CNS. *Id.* at 2.

The second report that Dr. Brown offered reacted to Dr. Cantor's opinion. Dr. Brown acknowledged the "possibility (and rare actuality)" that immunization could cause neurologic injury, but he disputed that this occurred to I.D. given the absence of persuasive proof in the medical records that she actually experienced any reaction (such as an encephalopathy) to the February 2011 vaccines. Second Brown Rep. at 1. He noted as well that Dr. Cantor's offered

literature mostly relied on studies involving the whole-cell pertussis vaccine, rather than the comparatively safer acellular version included in DTaP, and he went on to question the accuracy of certain other factual assumptions in Dr. Cantor's report. *Id.* at 2.[7]

III. Procedural History

As noted above, this action was initiated in October 2013. Petition at 1. After Petitioners filed some of the medical records relevant to their claim, the parties spent a few months considering settlement before Respondent determined in the spring of 2014 that amicable resolution of the case was unlikely. Petitioners subsequently filed their first expert report from Dr. Axelrod in October 2014 – prompting Respondent to state officially that settlement was no longer possible. After several months' delay, Respondent finally completed and filed his Rule 4(c) Report on February 6, 2015, recommending against compensation, accompanied by Dr. Brown's first expert report. ECF Nos. 36 and 37.

The following months saw the filing of the parties' two other reports – Dr. Cantor's in September 2015 (ECF No. 39), and a second report from Dr. Brown in August (ECF No. 47). The parties also devoted time in 2015 to disputing an interim fees request that Petitioners submitted in June, which I resolved by decision dated November 12, 2015 (ECF No. 53).

I thereafter requested that the parties propose a hearing date for resolution of Petitioners' claim, entering a pretrial order in February 2016 that set the matter for trial in March 2017. ECF No. 62. But in October 2016, the parties indicated during a status conference that they wished the hearing to be cancelled and the matter resolved instead on the basis of the written filed submissions and the existing medical record. I acceded to their request by Order dated October 20, 2016 (ECF No. 63), and I issued a schedule for filing briefs in support of, or opposition to, Petitioners' claim. The parties made their written submissions, and the matter is now ripe for resolution.

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[7] Petitioners have challenged Dr. Brown's competency to render an opinion in this matter, asserting that as a pediatric neurologist, he lacks the expertise to render an opinion on immunologic topics. Mot. at 18. In so arguing, they compare my treatment of Dr. Cantor's qualifications in a different case that I decided, *Wolf v. Sec'y of Health & Human Services*, No. 14-342V, 2016 WL 6518581, at *16 (Fed. Cl. Spec. Mstr. Sept. 15, 2016), where I found Dr. Cantor's opinion less persuasive for a similar reason. Mot. at 18 n.2.

Petitioners' point is well-taken in a general sense. Far too often in the Vaccine Program, the parties ask medical experts to opine on matters that exceed their primary expertise, or to recite the findings of medical or scientific literature relevant to a petitioner's case, without linking the testimony or statements to the expert's own qualifications or work. But in this case, the argument does not help Petitioners in proving their claim. For, as discussed below, my findings as to the insufficiencies of Petitioners' case principally arise from the unreliable or unpersuasive nature of *their own* expert reports – without any consideration of Dr. Brown's immunology arguments (although I do find that his points about the record, and knowledge of pediatric neurology, are helpful in evaluating whether the record itself reflects Petitioners' theory in action under *Althen* prong two). If *Wolf* suggests that I should give Dr. Brown's pronouncements on immunologic matters less weight, then that applies with greater force to Petitioners' expert, given that Petitioners bear the ultimate burden of proof herein.

IV. Parties' Respective Arguments

Petitioners maintain that they have established preponderant evidence in support of their causation-in-fact claim for each of the three prongs set forth by the Federal Circuit in *Althen v. Sec'y of Health & Human Servs.,* 418 F.3d 1274, 1278 (Fed. Cir. 2005). Mot. at 6-17. With respect to their obligation to establish a reliable causation theory, Petitioners propose that Dr. Axelrod (with assistance from Dr. Cantor) has done so by establishing that (a) the vaccines I.D. received were likely to cause upregulation of proinflammatory cytokines, (b) such cytokines have been shown to increase the permeability of the blood-brain barrier, (c) the same cytokines are pathogenic to the CNS, and (d) the tetanus toxoid found in the DTaP vaccine is itself pathogenic and binds to neurogangliosides in the brain, causing injury. *Id.* at 6-12.

For the second, "did cause" prong of the *Althen* test, Petitioners observe the fact that I.D.'s developmental problems all post-date her February 2011 vaccinations, and that (at least according to Mrs. Dean) she experienced an immediate reaction, which Dr. Cantor properly deemed indicative of an adverse response affecting her CNS. Mot. at 12-13 (citing Cantor Rep. at 1). They urge that Dr. Franz's views (which rest on Petitioners' uncorroborated statements about their observations of I.D.) about the real-world impact of the vaccinations (and particularly her decision to recommend a vaccine exemption for I.D.) merit weight since they come from a treater. Mot. at 14-15.

Finally, Petitioners argue that the timeframe in which I.D.'s vaccine reaction and subsequent developmental problems occurred is medically appropriate. They note that Dr. Axelrod's citation to Kashiwagi supports the conclusion about the immediate impact of the cytokine upregulation caused by vaccines. Mot. at 17 (citing Axelrod Rep. at 1). Otherwise, I.D.'s symptomatology occurred in a timeframe consistent with Dr. Axelrod's and Dr. Cantor's medical theories.

Respondent contests the adequacy of Petitioners' showing. In his opposition, he maintains that the medical record does not support Petitioners' contention that I.D. suffered any immediate neurologic injury post-vaccination related to her subsequently-manifesting developmental problems. Response at 6-7. In support, he references medical record evidence affirmatively establishing that I.D. was neurologically normal at that time. *Id.* at 8. He further maintains that Petitioners' causation theory is deficient, as it improperly leverages Kashiwagi and other items of literature to conclude that vaccine-induced cytokine production can have a number of pathologic impacts on an individual, when the existing science and medical literature largely does not support that assumption. *Id.* at 11-12. And Respondent proposes that Petitioners' experts lack sufficient background and expertise on the immunologic or molecular biologic issues implicated in their theory to opine reliably on these topics. *Id.* at 14-15.

Regarding the second and third *Althen* prongs, Respondent observes a lack of corroboration between Mrs. Dean's recollection of I.D.'s purported reaction to the vaccines and the record itself, and the record evidence that does include those reactions merely reflects second-hand repetition of things said to treaters rather than the treaters' own independent observations. Response at 15-16. The evidence, Respondent maintains, actually supports the conclusion that I.D.'s reaction was transient and/or insufficiently severe to cause the developmental problems she later experienced. *Id.* at 16-17. Respondent also questions the extent to which Petitioners' theory provides a reliable explanation for the timeframe from vaccination to onset of injury as set forth herein. *Id.* at 16.

Petitioners' reply begins with an attempt to defend Dr. Axelrod's credentials and expertise. Reply at 1-4. It then argues in favor of the scientific bases for Petitioners' theories, defending in detail Kashiwagi, Rochfort, and the other items relied upon most heavily by Drs. Axelrod and Cantor. *Id.* at 4-6. Petitioners go on to dispute the characterization of I.D.'s initial post-vaccine neurologic state as normal and seek to rebut Respondent's points about I.D.'s injury, such as Respondent's interpretation that I.D.'s EEG and examination by Dr. Davis were completely normal. *Id.* at 6-7. Petitioners contend that these points are incorrect, specifically alleging that her EEG did not mean that she was neurologically "normal," and instead only showed that she was not experiencing epileptiform activity during the testing. *Id.* Otherwise, Petitioners' reply repeats their earlier arguments that they have met their burden of proof to establish vaccine causation. *Id.* at 9-11.

V. Applicable Legal Standards

A. Claimant's Burden in Vaccine Program Cases

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury" – i.e., an injury falling within the Vaccine Injury Table – corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Human Servs*., 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Human Servs*., 440 F.3d 1317, 1320 (Fed. Cir. 2006).[8] In this case, Petitioner does not assert a Table claim.

[8] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Human Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd*, 104 F. App'x 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Human Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(a)(1)(A). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs*., 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Human Servs*., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim (which is the kind of claim asserted in this matter), a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen*: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278.

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citations omitted). To satisfy this prong, the petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id*. at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325-26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec'y of Health & Human Servs.*, 121 Fed. Cl. 230, 245 (2015) ("[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one" (emphasis in original)). But this does not negate or reduce a

petitioner's ultimate burden to establish his overall entitlement to damages by preponderant evidence. *W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record – including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 119, 136 (2011), *aff'd*, 463 F. App'x 932 (Fed. Cir. 2012); *Veryzer v. Sec'y of Health & Human Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd,* 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 Fed. App'x 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what

is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id*. at 1352; *Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 2013 WL 1896173 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Human Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. Law Governing Factual Determinations

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as "the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such a determination is evidenced by a rational determination).

Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (i.e., presenting all relevant information on a patient's health problems). *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Human Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Human Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). This presumption is based on the linked propositions that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Human Servs*., No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Human Servs*., 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms. It is equally unlikely that pediatric neurologists, who are trained in taking medical histories concerning the onset of neurologically significant

symptoms, would consistently but erroneously report the onset of seizures a week after they in fact occurred").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneously medical records are generally found to be deserving of greater evidentiary weight than oral testimony – especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd*, 968 F.2d 1226 (Fed. Cir.), *cert. den'd, Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Human Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Human Servs*., No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y Health & Human Servs*., 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records over contrary testimony, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. Analysis of Expert Testimony

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594-96 (1993). *See Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999)). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592-95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora (such as the district courts). *Daubert* factors are usually employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable and/or could confuse a jury. In Vaccine Program cases, by contrast, these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Human Servs.*, 94 Fed. Cl. 53, 66-67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742-45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts of his own in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Human Servs.*, No. 08-601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 Fed. App'x 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339).

D. Consideration of Medical Literature

Both parties relied on a few pieces of medical and scientific literature in this case to support their respective positions. I have reviewed all of the medical literature submitted in this case, although my decision does not discuss each filed article in detail. *Moriarty v. Sec'y of Health & Human Servs.,* No. 2015-5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted).

E. Determination to Resolve Case without Hearing

The parties have jointly agreed that I should decide entitlement in this case based on the written submissions and evidentiary filings, including each side's expert reports. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers rather than via evidentiary hearing, where (in the exercise of their discretion) they conclude that the former means of adjudication will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The choice to do so has been affirmed on appeal. *See Hooker v. Sec'y of Health & Human Servs.,* No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Human Servs.,* 38 Fed. Cl. 397, 402-03 (1997) (special master acted within his discretion in denying evidentiary hearing); *Burns,* 3 F.3d at 417; *Murphy v. Sec'y of Health & Human Servs.,* No. 90-882V, 1991 WL 71500, at *2 (Ct. Cl. Spec. Mstr. Apr. 19, 1991).

ANALYSIS

After careful review of the expert reports, medical records, and the competing arguments of both sides, and in light of my own accumulated experience resolving similar claims (as well as parallel decisions from other Vaccine Act cases), I conclude that Petitioners have not established preponderant evidence in favor of their claim.

A. Petitioners Have Not Shown that I.D. Experienced an Encephalopathy or Other Immediate Vaccine-caused Injury.

The record does not support Petitioners' conclusion that, more likely than not, I.D. experienced a post-vaccination encephalopathy or some other immediate reaction severe enough to later manifest as a neurologic injury. There is no credible proof in the record that I.D. suffered from an encephalopathy, seizures post-vaccination, a seizure disorder, or epilepsy or that her four-

month vaccinations caused any other medical problem. Rather, the records simply suggest that I.D. received the vaccinations in question, and then, about six weeks later, Mrs. Dean first began to inform treaters of the abnormal movements she saw I.D. displaying. At the same time, there *is* evidence in the same record undercutting claims of an alarming or abnormal reaction. Thus, I.D.'s EEG (a test which would more likely than not reveal neurological damage) on May 13, 2011, was normal (Ex. 2 at 69) and treaters such as Dr. Davis proposed an alternative diagnosis more consistent with the medical record.[9]

Petitioners propose to fill in the six-week gap in the records between vaccination and the first reports of I.D.'s developmental problems with Mrs. Dean's eyewitness accounts of I.D.'s purported reaction. Thus, to find for Petitioners, I would have to accept Mrs. Dean's recitations, along with her explanation that she opted not to inform treaters, or that I.D.'s physicians simply ignored her concerns and therefore did not write down what she told them. But Petitioners cannot establish that an event occurred simply based upon their uncorroborated allegations – especially where the contemporaneous proof rebuts those after-the-fact allegations. Section 13(a)(1); *Cucuras*, 993 F.2d at 1528. Rather, controlling law gives greater weight to written records, based on the reasonable proposition that an individual would more likely than not tell a treater of an observed medical problem or concern – and that in turn the treater (in the effort to provide the best care possible) would examine such concerns and take note of them.

To further bulwark allegations of I.D.'s reaction (as well as their contention that the February vaccines caused her symptoms), Petitioners offered the statement of Dr. Franz. There is no dispute that Dr. Franz was one of I.D.'s contemporaneous treaters, and it is well established in the Vaccine Program that "medical records and medical opinion testimony" of treating physicians can be "probative," because "treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury." *Capizzano*, 440 F.3d at 1326 (quoting *Althen*, 418 F.3d at 1278). But statements from treating physicians are not sacrosanct and can be rebutted and found by a special master to be unreliable or not dispositive in light of the record as a whole. Section 13(b)(1); *Snyder*, 88 Fed. Cl. at 746 n.67; *Davis v. Sec'y of Health & Human Servs.*, No. 07-451V, 2010 WL 1444056, at *14 (Fed. Cl. Spec. Mstr. Mar. 16, 2010).

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[9] It is instructive to compare the facts of this case with those exceedingly rare cases in which a claimant has established an encephalopathy following vaccination (although both are also distinguishable for another reason – as both involved Table claims in which causation was assumed). In one such instance, the vaccinated child developed a very high fever within 48 hours of vaccination, thereafter displaying crying, sleeplessness, and significant motor problems, all of which were documented in the medical record. *Poling v. Sec'y of Health & Human Servs.*, No. 02-1466V, 2011 WL 678559, at *1 (Fed. Cl. Spec. Mstr. Jan. 28, 2011). In another, the vaccinated child received a multi-virus vaccine and experienced a seizure on the trip home from the vaccination, followed by a week of noticeably decreased levels of consciousness and lethargy. *Wright v. Sec'y of Health & Human Servs.*, No. 12-423V, 2015 WL 6665600 (Fed. Cl. Spec. Mstr. Sept. 21, 2015). In Petitioners' case, by contrast, there are no contemporaneous records establishing any proximate temporal reaction to the vaccines that would support a finding that I.D. experienced such an encephalopathy.

This case provides a cogent example of the proper circumstances in which to give a treater opinion less weight than urged by a petitioner. As Dr. Franz's own declaration makes clear, many of the facts upon which her opinion is based were derived from the Deans's recitation of I.D.'s medical history, rather than from her own independent examinations or observations. *See* Franz Decl. at ¶ 3 ("[I.D.]'s parents are credible historians"). Indeed – Dr. Franz's declaration does not even say that she reviewed the medical record before offering an opinion. At the same time, the actual contemporaneous record (which Dr. Franz helped create as a treater) offers little to no support for her conclusions. When an expert relies on questionable or rebutted facts, that opinion is properly accorded less weight. *See Dobrydnev v. Sec'y of Health & Human Servs.,* 566 F. App'x 976, 983 (Fed. Cir. 2014) (expert's opinion based on facts that were not supported by a preponderance of the evidence were appropriately rejected by special master); *Davis v. Sec'y of Health & Human Servs.*, 20 Cl. Ct. 168, 173 (1990); *Raley v. Sec'y of Health & Human Servs.*, No. 91-732V, 1998 WL 681467, at *7 (Fed. Cl. Spec. Mstr. Aug. 31, 1998) ("the conclusions of an expert are only as sound as their factual predicate"). Accordingly, the conclusory diagnosis Dr. Franz gives, after the fact rather than at the time of treatment, has little probative value, and it is not redeemed by Dr. Franz's treater status in this case.

At the same time, contrary treater evidence exists that is more reliable and persuasive. Dr. Davis, I.D.'s treating neurologist (and thus more of a specialist in injuries relevant to the Petitioners' claim), evaluated I.D.'s medical condition and symptoms at the time (along with what the Deans told him), but deemed I.D.'s neurological status normal after examining her on May 13, 2011. Ex. 2 at 66-69. He characterized I.D.'s condition as "benign stereotypies," which he described as comparable to a childhood tic disorder. *Id.* at 67. And consistent with his overall diagnosis that her symptoms were not likely serious, I.D.'s "abnormal movements" resolved within one year, as Mrs. Dean noted in her visit with an occupational therapist on January 21, 2013. Ex. 4 at 72. Dr. Davis's diagnosis that I.D. suffered from idiopathic benign motor stereotypies that may have later been connected to other sequelae (but were not evidence of vaccine-caused neurologic injuries) is thus more consistent with the contemporaneous medical record than Dr. Franz's opinion.[10]

B. <u>Petitioners Have Not Established a Reliable or Persuasive Causation Theory.</u>

Petitioners' theory – that the DTaP and Hib vaccines, separately or in concert, could precipitate an encephalopathic event or other neurologic injury resulting in developmental problems – is unreliable, both on its own merits and also due to the insufficiencies of the expert reports offered in its support.

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[10] Petitioners argue in their Reply that Dr. Davis was not technically a "treating" physician because he only evaluated I.D. on one visit. However, an expert's opinion is not inherently deserving of less weight based on the length of time that a treater saw and evaluated the patient. Rather, as with any medical record, context matters – and here, the records from other treaters who may have seen I.D. more often do not persuasively rebut Dr. Davis's findings.

The most immediately apparent weakness in this case's causation theory is the heavy lifting it assigns to the post-vaccination cytokine production process as the cause of almost all of the pathologic effects of the vaccines at issue. Many of the general principles (as evidenced by Petitioner's expert reports plus the filed medical or scientific literature) that underlie this theory are not disputed. As Respondent specifically acknowledges, vaccination *inherently* induces the production of cytokines, and inflammation and fever are anticipated byproducts of a vaccine's administration. *See* Response at 11 n.11. In addition, it is understood that cytokines play a role in brain function – and specifically in protecting the brain from infection and damage. *Id.* at 12 n.12. And Petitioners have offered credible and reliable scientific literature, like Kashiwagi, that measures the increased production of cytokines post-vaccination, or that discuss the role cytokines may play in weakening the blood-brain barrier.

But science confirming or discussing the role that cytokines are known to play in the immunization process is not enough by itself to establish Petitioners' claim herein. Petitioners seek to demonstrate not just that vaccines induce cytokine upregulation, but that vaccines can do so pathologically, and for extended periods of time, sufficient *both* to cause a breach in the blood-brain barrier and subsequent damage to the brain, later manifesting as a developmental injury. Thus, in order to go beyond the general concepts that articles like Kashiwagi emphasize, the Petitioners required additional credible and reliable scientific or medical evidence – but they have not provided such proof.

Rather, Dr. Axelrod relies heavily on Kashiwagi, but it does not stand for the proposition cited. Not only was Kashiwagi's study not designed to examine the effects of cytokines in the brain following vaccination, but its central purpose (comparing the levels of inflammatory cytokines in the sera of vaccine recipients with febrile and non-febrile illnesses within 24 hours of vaccination) does not shed light on whether the particular kinds of cytokines produced in the study could cause the injury proposed herein (a CNS-oriented injury, as opposed to peripheral cytokine changes occurring at the locus of vaccination).

Beyond the above, neither Kashiwagi nor any other literature that Petitioners cite establishes that cytokine upregulation could be maintained biologically for long enough, and in sufficient quantities as well, to act as Dr. Axelrod's theory proposes. In fact, Kashiwagi's study shows that cytokine production increased only for approximately 24 hours following stimulation. Kashiwagi at 3. Further, the only increased cytokine identified in the serum of the test subjects was an elevated G-CSF level in individuals with a febrile illness, and the authors were unable to determine the significance of this result. *Id.* The decisions of other special masters (albeit not in precisely the same circumstances) have noted that Kashiwagi does not support the idea that cytokines produced in response to vaccination could negatively impact the brain in the way Dr. Axelrod proposes herein. *See, e.g., Copenhaver v. Sec'y of Health & Human Servs.*, No. 13-1002V, 2016 WL 3456436, at *9-14 (Fed. Cl. Spec. Mstr. May 31, 2016) (infant's death not caused by

cytokine upregulation due to vaccination), *mot. for review den'd,* 129 Fed. Cl. 176 (2016); *Cozart v. Sec'y of Health & Human Servs.*, No. 00-590V, 2015 WL 6746499, at *6-7 (Fed. Cl. Spec. Mstr. Oct. 15, 2015), *mot. for review den'd,* 126 Fed. Cl. 488 (2016)

Petitioners rely in turn on Rochfort to show how cytokines could theoretically increase the permeability of the blood-brain barrier. At the outset, however, it is worth noting that Rochfort was an *in vitro* study, and thus may not necessarily be illuminating when proposed for an *in vivo* process – a fact the study itself admits. *See* Rochfort at 7. Rochfort also notes that cytokines are not even necessarily understood to be toxic to the brain. *See id.* ("several studies also report evidence of a neuroprotective role for [TNF alpha] in the brain"). And in any event, Rochfort suffers from some of the same limiting factors as Kashiwagi (*i.e.* not addressing vaccines). Thus, even if Rochfort offers some support for Petitioners' theory, it is not enough by itself to establish preponderant evidence that vaccination would more likely than not allow permeation of the blood-brain barrier simply due to cytokine upregulation expected to be caused by the vaccine in the first place.

All in all, there is a sweeping quality to this element of Petitioners' theory. All vaccinations could potentially cause the pathologic cytokine upregulation Dr. Axelrod's theory proposes, along with the increase in the blood-brain barrier's permeability and concurrent toxic interaction – simply through the working of the body's innate immune reaction to vaccination. If so, there should be plenty of research supporting this theory and bulwarking Petitioners' contentions – if not with respect to all vaccines, then at least in connection with the ones at issue herein. But no such evidence has been offered – and even though Petitioners need not offer literature to prove their case, the absence of such additional proof greatly undermines the reliability of this part of their theory.

The side of Petitioners' theory addressing the allegedly pathologic nature of components of the DTaP vaccine similarly lacks scientific reliability. Petitioners allege that whatever amount of tetanus toxoid is found in the DTaP vaccine is enough to bind to site receptors in the brain, and they offer case reports about adverse events associated with the pertussis vaccine in support of this contention. *See* Exs. 19-22, 26, 29. But they bulwark these contentions with fairly outdated literature, literature involving the whole-cell DPT form of the vaccine, or both. Petitioners simply have not shown that the *acellular* form of pertussis toxoid contained in DTaP would necessarily have the same effect as the whole-cell formulation – or that it would cause the specific injury in this case. In fact, likely the opposite is true. *See, e.g.*, *Taylor v. Sec'y of Health & Human Servs.*, 108 Fed. Cl. 807, 820 (2013) (noting that the modern DTaP vaccine has evolved from attempts to minimize the amount of toxin in the vaccine as compared to past versions); *James v. Sec'y of Health & Human Servs.*, No. 09-284V, 2010 WL 4205699, at *11 (Fed. Cl. Spec. Mstr. Sept. 30, 2010) (stating that the acellular form of the pertussis vaccine is much less toxic than the whole-cell form).

Respondent has also raised legitimate points about Dr. Axelrod's competency to offer the theory espoused in this case. Dr. Axelrod is certainly the only immunologist to render an opinion in this case, and as such I have taken his report seriously and given it primary consideration on such topics. But it is undeniable that despite his general competency to opine on immunology, he lacks demonstrated specific experience in studying cytokine function, the particular vaccines at issue, or their propensity to cause developmental injuries of the sort alleged herein.[11] He cannot represent that he has direct, relevant experience such that I should credit his opinions even in the absence of scientific or medical literature supporting Petitioners' theory. A theory does not obtain additional reliability simply because it comes from an immunologist, when that immunologist has no demonstrated expertise in the specific issues in question.[12] *See Snyder v. Sec'y of Health & Human Servs.,* 553 Fed. Appx. 994, 1000-02 (Fed. Cir. 2014) (special master was not arbitrary and capricious in rejecting testimony of expert who had read literature to support an opinion, but had no individual experience treating patients with the relevant disease); *Daubert*, 43 F.3d at 1317 ("[o]ne very significant fact to consider is whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying"). Here, I find that Dr. Axelrod's opinion was less persuasive due to this lack of specific familiarity and expertise on the vaccines and injuries directly at issue.

C. The Remaining *Althen* Prongs have not Been Satisfied.

Although I have only specifically discussed the deficiencies in Petitioners' *Althen* prong one showing, their claim fares no better under the other two prongs.

First, Petitioners have not established that their theory about the role of vaccine-induced cytokines causing a neurologic injury is reflected in the medical history (the "did cause," or second *Althen* prong). As already noted, there is no record evidence that I.D. experienced a severe reaction to her five-month vaccinations outside of Petitioners' own after-the-fact claims – and those claims are not corroborated by other evidence, such as lab results or testing. Meanwhile, there is persuasive contrary evidence (Dr. Davis's conclusions, the normal EEG results, etc.) suggesting that I.D. was in fact *not* experiencing a damaging neurologic reaction. Petitioners can point to nothing else that would demonstrate the cytokine upregulation they posit was occurring in the period between February 24, 2011, and mid-April of that year (I.D.'s next visit with Dr. Franz), or

[11] Dr. Axelrod's ability to successfully opine about cytokines has been questioned before by other special masters. *See, e.g., Copenhaver*, 2016 WL 3456436, at *9.

[12] As previously noted, Petitioners are not incorrect in observing that Respondent's expert, Dr. Brown, himself lacks direct or extensive immunologic expertise – but that does not mean that Dr. Axelrod's opinions must be accepted simply because he is more credentialed in the topic. Indeed – since Petitioners bear the burden of proof, it is the competency of their own experts that is most important.

that she experienced an encephalopathy, whether or not autoimmune in nature. At most (and crediting Mrs. Dean's testimony generally), the evidence would support the conclusion that I.D. experienced a local, transient reaction to her vaccination that resolved without the need for serious medical intervention.

Second, Petitioners have not demonstrated a medically acceptable timeframe to explain the biological course of I.D.'s injury, from the February 24, 2011, vaccinations to manifestation of developmental symptoms later that spring (at earliest). Accepting Petitioners' uncorroborated allegations, I.D.'s first symptoms began shortly after vaccine administration (evidenced by her purported crying, fever, and vomiting) and then around two weeks later presented in the form of her "abnormal" hand movements. This timeframe is somewhat consistent with Dr. Axelrod's proposed (albeit vaguely-outlined) time period for the cytokine upregulation, but his theory does not fully explain the gap between the neurologic component of I.D.'s injury and her immediate purported reactions to the vaccines. And even if it did, the medical records (which, as already stated several times, contain no mention of an alleged reaction or symptoms at I.D.'s March 17th pediatric visit) are not wholly consistent. I also note that Petitioners' inability to corroborate their allegations about the vaccine reaction and process of injury with medical record proof further diminishes their argument that the injury occurred in a reasonable timeframe following the date of vaccination. At bottom, Petitioners are relying on a mere temporal post-vaccination manifestation of a developmental injury that, without some additional evidence to show events were unfolding as would be predicted, is insufficient to meet their preponderant evidence burden.

Based upon my overall review of the medical records, along with competing treater explanations for I.D.'s condition, I find it is <u>not</u> "more likely than not" that I.D.'s developmental problems were related to her receipt of DTaP or Hib vaccines. Rather, the evidence more persuasively suggests (in line with Dr. Davis's diagnosis) that I.D. experienced idiopathic benign motor stereotypies after vaccination, and sometime thereafter experienced some developmental sensory challenges and minor expressive language delay that were unrelated to the vaccinations.

CONCLUSION

The record does not support the Deans's contention that the vaccines I.D. received in February 2011 could, or did, cause her subsequent developmental symptoms. Petitioners have not established entitlement to a damages award, and therefore I must **DISMISS** their claim.

In the absence of a timely-filed motion for review (see Appendix B to the Rules of the Court), the Clerk shall enter judgment in accordance with this decision.[13]

IT IS SO ORDERED.

/s/ Brian H. Corcoran
Brian H. Corcoran
Special Master

[13] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.